



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,765	04/04/2001	Yumi Yokoyama	600.491US2	3671

7590

07/29/2003

Schwegman, Lundberg, Woessner & Kluth, P.A.
P.O. Box 2938
Minneapolis, MN 55402

EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 07/29/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/825,765

Applicant(s)

YOKOYAMA ET AL.

Examiner

Sheela J Huff

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-28 and 31 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 29 and 30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

In the instant application the section is incomplete.

After a careful review of the parent application and the provisional application, the Examiner has determined that claims 1, 5-8, 11, 13-14, 18, 21-24 have priority to 4/3/00 while the remaining claims have priority to 4/3/01.

Information Disclosure Statement

The IDS filed 3/1/02 has been considered and an initialed copy of the PTO-1449 is enclosed.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Art Unit: 1642

Applicant is directed to page 10, lines 18 and 22.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8, 11-16, 18-28 and 31 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-26 of copending Application No. 09/825129. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

Art Unit: 1642

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-8, 11, 12, 13, 15, 17-19, 21, 22, 25 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Publication No. 2002/0193326 (filed 7/1/99).

This reference discloses the formation of chimeric or fusion proteins, using recombinant techniques, comprising, two or more known anti-angiogenic proteins (which include endostatin and angiostatin) and a targeting agents (such as EGF or RGD peptides) (see page 6, paragraph [0046]). This reference also discloses timed release or sustained release compositions of the invention (see page 10, paragraph [0083]). This reference also discloses that other known anti-angiogenic proteins can also be used , such as Tumstatin, Canstatin, Resin (see page 15, paragraph [0123]).

The only difference between the reference and the claimed invention is that the reference does not specifically make the chimeric protein using recombinant techniques.

However, in view of the explicit suggestion in the reference to make such proteins using recombinant techniques, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to make the claimed fusion proteins.

Claims 1, 5-8, 11, 12, 13, 15-19, 21, 22, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Publication No. 2002/0193326 (filed 7/1/99) in view of applicant's admission on pages 2 and 26 of the specification.

The primary reference has been discussed above.

The only difference between the instant invention and the reference is the use of alginate beads in the sustained release composition and the use of other anti-angiogenic proteins claimed in claim 12 and 27.

However, on page 26 of the specification, applicant admits that the use of alginate beads in such compositions is known in the art. On page 2 of the specification, applicant admits that the proteins claimed in claim 12 and 27 are known in the art.

In view of this, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use alginate beads in the sustained release composition. It also would have been obvious to use any known anti-angiogenic protein instead on endostatin or angiostatin in the fusion protein.

Claims 1-8, 11-16, 18-22, 25-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Publication No. 2002/0193326 (filed 7/1/99) in view of Arap et al Science vol. 279 p. 377 (1996) and applicant's admission on pages 2 and 26 of the specification.

The primary reference has been discussed above.

The only difference between the instant invention and the reference is the use other RDG peptides, such as NGR containing peptides, a sustained release formulation and the use of alginate beads in the sustained release composition.

Arap et al disclose conjugates comprising either CNGRC or RGD containing peptide and dox and the use of these to target drugs to tumors. Thus, the reference is teaching that both types of peptides are effective in delivering the drug.

On page 26 of the specification, applicant admits that the use of alginate beads in such compositions is known in the art. On page 2 of the specification, applicant admits that the proteins claimed in claim 12 and 27 are known in the art.

In view of Arap, it would have obvious to one of ordinary skill in the art at the time of applicant's invention to use either NGR-containing peptides or RGD-containing peptides to deliver the endostatin or angiostatin to the tumor. The formulation of a sustained release composition would also have been obvious in view of the primary reference. It also would have been obvious to use alginate beads in the sustained release composition. It also would have been obvious to use any known anti-angiogenic protein instead on endostatin or angiostatin in the fusion protein.


Allowable Subject Matter

Claims 9, 10 and 29-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Sheela J Huff
Primary Examiner
Art Unit 1642